

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0986272	(X3) Date Survey Completed 01/27/2022
Name of Provider or Supplier Uab Cancer Center At Russell Medical	Street Address, City, State 3446 Highway 280, Alexander City, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Sysmex XP-300 Hematology analyzer calibration records and an interview with the Technical Consultant, the laboratory failed to ensure the calibration verification was performed every six months, as per manufacturer's requirements. This was noted on one of two 2021 calibrations reviewed. The findings include: 1. A review of the Sysmex XP-300 calibration records revealed a calibration was performed on 2/18/2021 by a Sysmex service technician. The Sysmex Service Maintenance Certificate documented the 2/18/2021 calibration verification expired on 8/17/2021, however the next calibration verification was not performed until 11/4 /2021. 2. During an interview on 1/27/2022 at 1:40 PM, the surveyor reviewed the Sysmex calibration records with the Technical Consultant, and asked why the second calibration verification in 2021 was performed approximately three months late. The Technical Consultant stated usually the Sysmex service technician performed the calibration when it was due, and she did not know why it was late. The surveyor then</p>

asked if anyone in the laboratory monitored when the calibration verification was due to ensure it was performed on time; the Technical Consultant confirmed the laboratory had not. .

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the Sysmex XP-300 calibration certificates, Quality Assurance (QA) records and an interview with the Technical Consultant, the laboratory failed to note the calibration verification had expired in the September and October 2021 QA reviews. The findings include: 1. A review of the Sysmex XP-300 calibration records revealed a calibration was performed on 2/18/2021 by a Sysmex service technician. The Sysmex Service Maintenance Certificate documented the 2/18/2021 calibration verification expired on 8/17/2021, however the next calibration verification was not performed until 11/4/2021. (Refer to D5437.) 2. A review of QA records revealed the laboratory checked the boxes next to "Calibration", "Present and up to date", and "Acceptable" for the calibration. This occurred in September and October 2021 (after the 8/17/2021 expiration). 3. During an interview on 1/27/2022 at 2:15 PM, the surveyor reviewed and confirmed the above noted findings with the Technical Consultant. SURVEYOR ID# 32558 Licensure and Certification Surveyor